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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,946	03/08/2004	Denis Pichon	OSTEONICS 3.0-454	1423

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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09/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/795,946

Applicant(s)

PICHON ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-19 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-19 and 24-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11,13,28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11,13 recite the limitation "the shoulder" in lines 3 and 2 respectively in the claims. There is insufficient antecedent basis for this limitation in the claims.

Claim 28 recites the limitation "the trial proximal sleeve" in line 11 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,11-13,16-19,28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scharbach et al. (3987499) in view of Ferree (2004/24469). Scharbach et al. disclose (Fig. 9) a femoral prosthesis having a stem **113** and a neck **132** of which is attached to the stem via means in the form of a screw **129**. It can be construed that the part that receives the screw forms a shoulder. It can be seen that a sleeve 140 surrounds the neck with the interior being the same shape and the outer

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surface being of an alternatively shaped part-circumferential structure. It can also be seen (Fig. 9) that the neck has means in the form of threads **137** to attach to ball head **135**. However, Scharbach et al. fail to disclose the sleeve formed as two components. Ferree teaches (Figs. 8A,8B) that sleeves for femoral prostheses can be formed as two parts with screws to tighten the two pieces together. It can be seen that troughs are formed in the inner surfaces of the sleeve components to match the surface of the prosthesis. Ferree also teaches that this structure permits the sleeve to be tightened and adjusted to a degree for decreasing motion between the prosthesis and bone, paragraphs 73,74. It would have been obvious to one of ordinary skill in the art to utilize adjustable means and two sleeve components as taught by Ferree with the prosthesis of Scharbach et al. such that the surgeon can adjust the implant within the patient's intramedullary canal to a set position and prevent movement.

Claims 14,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scharbach et al. (3987499) in view of Ferree (2004/24469) as applied to claim 13 above, and further in view of Draenert et al. (6706073). Scharbach et al. in view of Ferree is explained supra. However, Scharbach et al. as modified by Ferree fail to disclose a tapered portion on the stem to attach with the neck. Draenert et al. teach (Figs. 1.1,4) that the prosthesis can be made with a tapered neck portion to attach with fastening means. It would have been obvious to one of ordinary skill in the art to utilize tapered portions on the stem for attachment with the neck and screw as taught by Draenert et al. in the prosthesis of Scharbach et al. as modified by Ferree such that it provides a more secure fit.

Claims 2-8,29,30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scharbach et al. (3987499) in view of Ferree (2004/24469) as applied to claims 1,28 above, and further in view of Noiles (4846839). Scharbach et al. in view of Ferree is explained supra. However, Scharbach et al. as modified by Ferree fail to disclose the sleeve components are located on the sides of the stem. Noiles shows (Fig. 1) a femoral sleeve that has a length that extends from the shoulder and neck area at the proximal end of the stem downward on the lateral and medial sides of the stem. It would have been obvious to one of ordinary skill in the art to lengthen the sleeve to extend on the sides of the stem as taught by Noiles with the femoral prosthesis of Scharbach et al. as modified by Ferree such that it provides a stronger neck and proximal supported stem area since this is where the load is placed at the joint.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scharbach et al. '499 in view of Ferree (2004/24469) and Fallin '452. Scharbach et al. in view of Ferree is explained supra. Scharbach et al. does disclose a neck coupled to and extending medially from the stem. As mentioned above Scharbach et al. fails to disclose two sleeve portions and a plurality of prosthetic femoral components. Fallin teaches a plurality of prosthetic femoral components, Figs. 1,3,4. Fallin also teaches that it is advantageous to provide a kit or plurality of components for the surgeon to use to enable the surgeon to properly fit a prosthesis in the patient according to the anatomical dimensions encountered, col. 3, lines 31-37. Fallin additionally teaches separate neck portions attachable to the stem. It would have been obvious to one of ordinary skill in the art to provide a kit of components and utilize adjustable means and

two sleeve components as taught by Fallin and Ferree respectively with the prosthesis of Scharbach et al. such that the surgeon can properly adjust the implant within the patient's intramedullary canal to a set position and prevent movement.

Response to Arguments

Applicant's arguments with respect to claims 1,24,28 have been considered but are moot in view of the new ground(s) of rejection. The Examiner did note that the Applicant's remarks commented on the Ferree reference and that the sleeve is expanded. However, Ferree does teach that the expanding is done to just provide a stable fit in the bone canal and then the stem is firmly position within the bore of the sleeve. Ferree explicitly states the stem is immobilized and thus is advantageous.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the


shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (9am-5:30pm) .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738


BRIAN E. PELLEGRINO
PRIMARY EXAMINER